DEPARTMENT OF THE NAVY
NAVAL HOSPITAL
BOX 788250
MARINE CORPS AIR GROUND COMBAT CENTER
TWENTYNINE PALMS, CALIFORNIA 92278-8250

IN REPLY REFER TO:
NAVHOSP29PALMSINST 6320.62C
Code 0504
2 December 1996

NAVAL HOSPITAL TWENTYNINE PALMS INSTRUCTION 6320.62C

From: Commanding Officer

Subj: PHARMACY AND THERAPEUTICS COMMITTEE

Ref: (a) Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), Accreditation Manual for Hospitals, current edition
(b) OPNAVINST 5420.27J
(c) MANMED Chapter 21, Change 103, 109

Encl: (1) Non-formulary Drug Request, NAVHOSP29PALMS Form 6710/01
(2) Request for Addition of Medication to Formulary, NAVHOSP29PALMS Form 6710/02

1. Purpose. To establish functions and composition of the Pharmacy and Therapeutics Committee for Naval Hospital Twentynine Palms, California.

2. Cancellation. NAVHOSP29PALMSINST 6320.62B.

3. Background. Pursuant to references (a) and (b), the Pharmacy and Therapeutics Committee is established to develop and recommend policies and procedures for selecting, distributing, handling, using, and administering drugs and diagnostic testing materials. The committee may appoint subcommittees as deemed necessary.

4. Composition. The Pharmacy and Therapeutics Committee shall be chaired by the Head, Internal Medicine, appointed by the Commanding Officer, and comprised of the following multi-disciplinary members:

a. Head, Pharmacy Department (Recorder)

b. Head, Emergency Department

c. Dental Representative (Ad-Hoc)

d. Surgical Services Directorate Representative

e. Medical Services Directorate Representative

f. Head, Fiscal Department

g. Nursing Services Directorate Representative

h. Other Ad-Hoc members as requested by the Chairman

5. Action

a. The Pharmacy and Therapeutics Committee shall:

(1) Develop and maintain a drug formulary. (A minimum of one formulary or drug class review will be performed during the last meeting of the calendar year.)

(2) Review submissions for additions, revisions, or purchases of non-formulary items.

(3) Evaluate and approve protocols concerned with the use of investigational or experimental drugs.

(4) Define and review all adverse drug reactions (ADR).

(a) An Adverse Drug Reaction is any detrimental response to medications that is undesired, unintended or unexpected in doses recognized in accepted medical practice and results in:

(1) Hospitalization.

(2) Discontinuation of drug therapy.

(3) Cause a change in drug therapy.

(4) Require corrective measures such as antidotes.

(b) REPORTING A SUSPECTED ADR: The reporting of suspected ADR's within the Naval Hospital is important for the protection of patients experiencing reactions and for the sharing of clinical experiences among members of the medical staff. The reporting of ADR's to the Food and Drug Administration enables that organization to compile data from many sources and attach statistical significance to them. Reports of ADR's will be used to determine the following:

(1) Whether additional controlled studies should be performed on the medication.

(2) Whether the medication should be restricted to certain prescribers or special situations.

(3) Whether use of the medication should be suspended immediately.

(c) WHAT NOT TO REPORT: The following ADR's need not be reported:

(1) Blood transfusion reactions, unless there is a suspected defect in the anticoagulant substances. Blood transfusion readings will be reported to the laboratory in accordance with NAVHOSP29PALMSINST 6530.1.

(2) Poisoning with household substances or medications.

(3) Well known and extensively documented reactions.

(4) Instances where the adverse effect, even though untoward, is simply an exaggerated manifestation of a known effect of the medication.

(5) Minimal side effects such as nausea.

(d) ACTION: ADR's will be reported to the prescribing practitioner immediately upon discovery. An entry of the medication given and the reaction will be properly recorded in the patient's medical record.

(1) The responsible practioner, in conjunction with the pharmacist, will prepare an FDA MEDWATCH form 3500, Adverse Reaction report.

(2) The Head, Pharmacy Department will forward the completed form to the Pharmacy and Therapeutics Committee for consideration and recommendation for further action. If recommended by the Committee and approved by the Commanding Officer, the Head, Pharmacy Department will then forward the form to the FDA. A copy of the report will be retained in the pharmacy.

(3) The Head, Pharmacy Department will also monitor and obtain data on ADR's regarding occurrences, frequencies and trends, This information will be forwarded to the Pharmacy and Therapeutics Committee for action.

(e) Conclusions, recommendations, actions taken and evaluations will be reported in the minutes as outlined in reference (c).

(f) The committee will review the definition of adverse drug reactions at least annually.

(1) Review, make recommendations, and approve the findings of drug and antibiotics reviews performed by the medical staff.

(2) Conduct an annual review of the formulary and pharmacy related policies or protocols.

(3) Risk management will report medication errors to the Pharmacy and Therapeutics committee quarterly for submission into the quarterly Pharmacy and Therapeutic minutes.

(4) Pharmacy Department will submit a Quality Assurance report for inclusion into the quarterly Pharmacy and Therapeutic minutes.

(5) The Pharmacy and Therapeutics committee chain of command for routing minutes is as follows.

(a) Performance Improvement Coordinator.

(b) Executive Committee of the Medical Staff.

(c) Executive Officer.

(d) Commanding Officer.

b. Head, Pharmacy Department (Recorder) shall:

(1) Distribute agenda for meetings at least three days prior to committee convening.

(2) Prepare and submit minutes in accordance with reference (d) within five working days after meeting convened.

c. Healthcare providers shall use the approved formulary. Requests for one time pharmaceuticals, such as special medication for use by an individual patient, that are not listed on the formulary, shall be requested using enclosure (1). Requests for

changes to the formulary to meet recurring or changes in recommended treatment regimens, should be submitted using enclosure (2).

6. New or Revised Forms: Non-formulary Drug Request, NAVHOSP29PALMS Form 6710/01, enclosure (1) and Request for Addition of Medication to Formulary, NAVHOSP29PALMS Form 6710/02, enclosure (2) are being adopted per this instruction and can be obtained through Central Files.

R. S. KAYLER

Distribution:
List A and I

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IN REPLY REFER TO:

NAVHOSP29PALMSINST 6320.62C CH-1
Code 0504
4 August 1997

NAVAL HOSPITAL TWENTYNINE PALMS INSTRUCTION 6320.62C CHANGE TRANSMITTAL 1

From: Commanding Officer

Subj: **PHARMACY AND THERAPEUTICS COMMITTEE**

1. **Purpose**. To direct a pen and ink change to the basic directive.

2. **Action**. On page 1 paragraph 4, delete the words "the Head, Internal Medicine Department" and insert "a Medical Corps Officer" in lieu of.

J. A. NORTON
By direction

Distribution:
List A

NAVHOSP29PALMSINST 6320.62C
2 December 1996

NON-FORMULARY DRUG REQUEST

1. DRUG, STRENGTH AND DOSAGE FORM REQUIRED

2. FORMULARY ITEMS CONSIDERED/USEDREASON FOR NOT USING

3. DIAGNOSIS

4. COMPLICATING FACTORS

5. DATE DRUG IS REQUIRED

6. INTENDED LENGTH OF THERAPY (If length of treatment exceeds three months, submit a request to the Pharmacy and Therapeutics Committee for formulary addition)

7. PATIENT'S NAME AGE PT IDENTIFICATION NUMBER

8. SIGNATURE OF PRESCRIBER

_____

9. AUTHORIZED SIG OF DIRECTOR MEDICAL/SURGICAL

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SECTION BELOW IS FOR PHARMACY USE ONLY

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REQUESTING DRUG'S AMERICAN HOSPITAL FORMULARY SERVICE CATEGORY NUMBER

FORMULARY ITEMS IN CATEGORY NOT INCLUDED ABOVE

DATE ORDERED	DATE RECEIVED	SOURCE	COST
_____	_____	_____	

PROCESSED BY:

NAVHOSP29PALMS Form 6710/01 (Rev. 11/96)

Enclosure (1)

REQUEST FOR ADDITION OF MEDICATION TO FORMULARY

DATE:

From:	**Department:**
To: Chairman, Pharmacy and Therapeutics Committee **Via: (1) Department Head** **(2) Head, Pharmacy Department**	
Name of Drug (Generic):	**(Trade Name):**
Dosage Form: (circle one) **Solid/Oral Liquid Injection Suppository** **Other (please explain):**	
Manufacturer:	**Estimated Usage Rate:**
Purpose for addition:	
Will item requested replace/supplement drug currently available in Pharmacy:	
Signature:	

First Endorsement

From: Department Head, Pharmacy		**Date:**
Remarks:		
Proposed restrictions:		
Cost per dose:	**Cost per day:**	**Cost per course:**
Signature:		

Second Endorsement

From: Department Head,_____	**Date:**
Remarks:	
Proposed restrictions:	
Signature:	

Action of Pharmacy and Therapeutics Committee

Approved: Yes No	**Date:**
Restrictions?:	
Trial period?:	**Review month/year:**

Comments:
NAVHOSP29PALMS Form 6710/02 (Rev. 11/96)